

Amendments to the Claims

Claim 1 (Withdrawn): A composition for modulating a physiological reaction or inducing an immune response in human or animal after oral administration, said composition comprising:

- a) at least one physiologically active agent;
- b) at least one neutralizing agent effective to increase pH in digestive system of said human or animal to prevent denaturation of said physiologically active agent;
- c) at least one inhibitor of digestive enzymes to prevent enzymatic digestion of said physiologically active agent, said inhibitor being selected from the group consisting of homogenized legumes, oilseed or pulse grains; and
- d) at least one uptake-increasing agent capable of increasing intestinal absorption of said physiologically active agent.

Claim 2 (Withdrawn): The composition of claim 1, wherein said neutralizing agent is at concentration between 1% to 60% w/w, said inhibitor is at concentration between 1% to 50% w/w, and said uptake increasing agent is at concentration between 0.1% to 50% w/w

Claim 3 (Withdrawn): The composition of claim 1, wherein said physiologically active agent is selected from the group consisting of therapeutical agents, nutritional products, mucopolysaccharides, lipids, carbohydrates, steroids, hormones, growth hormones (GH), growth hormone releasing hormones (GHRH), epithelial growth factors, vascular endothelial growth and permeability factors (VEGPF), nerve growth factors,

cytokines, interleukins, interferons, GMCSF, hormone-like products, neurological factors, neurotropic factors, neurotransmitters, neuromodulators, enzymes, antibodies, peptides, proteic fragments, vaccines, adjuvants, antigens, immune stimulating or inhibiting factors, hematopoietic factors, anti-cancer products, anti-inflammatory agents, anti-parasitic compounds, anti-microbial agents, nucleic acid fragments, plasmid DNA vectors, cell proliferation inhibitors or activators, cell differentiating factors, blood coagulation factors, immunoglobulins, negative selective markers or "suicide" agents, toxic compounds, anti-angiogenic agents, polypeptides, anti-cancer agents, acid production drugs, and histamine H₂-receptor antagonists.

Claim 4 (Withdrawn): The composition of claim 1, wherein said neutralizing agent is in an amount sufficient to neutralize acidic degradation in said human or animal digestive system and to allow delivery of said physiologically active agent to intestine of said human or animal.

Claim 5 (Withdrawn): The composition of claim 1, wherein said neutralizing agent is selected from the group consisting of anti-acids, sodium bicarbonate, sodium carbonate, sodium citrate, calcium phosphate, calcium carbonate, magnesium salts, magnesium carbonate, magnesium trisilicate, magnesium hydroxide, magnesium phosphate, magnesium oxide, bismuth subcarbonate, and combinations thereof.

Claim 6 (Withdrawn): The composition of claim 1, wherein said neutralizing agent is at least one of sodium carbonate at a concentration of 10% to 20% w/w, and calcium carbonate at concentration of 10% to 20% w/w of the composition.

Claim 7 (Withdrawn): The composition of claim 1, wherein said inhibitor is in an amount sufficient to inhibit degradation of said physiologically active agent by digestive enzymes in said human or animal digestive system and to allow delivery of said physiologically active agent to intestine of said human or animal.

Claim 8 (Withdrawn): The composition of claim 1, wherein said inhibitor of digestive enzymes is selected from the group consisting of anti-protease, egg albumin, plant-derived inhibitors from oilseed, soybean, kidney bean, faba bean, rice bran, wheat bran, ethylenediamine tetraacetate, alpha-1-antitrypsin, albumin, ovalbumin, and proteosomes.

Claim 9 (Withdrawn): The composition of claim 1, wherein said inhibitor comprises at least one of a pepsin inhibitor and an enteropeptidase inhibitor.

Claim 10 (Withdrawn): The composition of claim 1, wherein said inhibitor is albumin at a concentration between 1% to 20% w/w.

Claim 11 (Withdrawn): The composition of claim 1, wherein said uptake increasing agent is selected from the group consisting of a bile salt, saponin, deoxycholate, sodium

salicylate, sodium lauryl sulphate, oleic acid, linoleic acid, monoolein, lecithin, lysolecithin, polyoxyethylene sorbitan ester, p-t-octylphenoxy polyoxyethylene, N-lauryl-beta-D-maltopyranoside, 1-dodecylazacycloheptane-2-azone, and phospholipid.

Claim 12 (Withdrawn): The composition of claim 11, wherein said uptake-increasing agent is deoxycholate at a concentration between 0.01% to 10%.

Claim 13 (Withdrawn): The composition of claim 1 comprising at least one additional ingredient selected from the group consisting of ethylenediamine tetraacetate, a preservative, an antioxidant, a colorant, a binder, a tracer, a sweetener, a surfactant, an unmoulding agent, a flavouring agent, meal, bean, yeast, brewer yeast, mineral oil, vegetable oil, animal oil, a lubricant, an ointment, and combinations thereof.

Claim 14 (Withdrawn): The composition of claim 1, wherein said physiologically active agent when delivered in intestine of said human or animal is absorbed by said intestine for systemic delivery.

Claim 15 (Withdrawn): The composition of claim 1, wherein said physiologically active agent when delivered in intestine of said human or animal has an effective physiological effect on intestinal wall.

Claim 16 (Withdrawn): The composition of claim 1, wherein said physiologically active agent when delivered in intestine of said human or animal has a physiological effect on the content of the intestine.

Claim 17 (Withdrawn): The composition of claim 1, wherein said animal is a bird, a mammal, an insect, a crustacean, an amphibian, a reptile or a fish.

Claim 18 (Withdrawn): The composition of claim 1, wherein said physiologically active agent is capable of inducing an immune response in said human or animal against mucosal infectious diseases.

Claim 19 (Withdrawn): The composition of claim 1, wherein said modulating comprises increasing or reducing the rate of a physiological reaction.

Claim 20 (Withdrawn): A method for modulating a physiological reaction or inducing an immune response in a human or an animal comprising orally administering to said human or animal a sufficient amount of a composition as defined in claim 1.

Claim 21 (Withdrawn): The method of claim 20, wherein said physiological reaction is at least one of body growth, immune reaction, fat metabolism, or muscle synthesis.

Claim 22 (Withdrawn): A method of systemic delivery of a physiologically active agent to a human or an animal, said method comprising orally administering to said human or animal a composition as defined in claim 1.

Claim 23 (Currently amended): A method for enhancing body uptake of a physiologically active agent or an antigen in a human or an animal to modulate a physiological reaction or induce immune response comprising: orally administrating to said human or animal at least one physiologically active agent; neutralizing the pH in digestive system of said human or animal to prevent denaturation of said physiologically active agent; inhibiting digestive enzymes to prevent enzymatic digestion of said physiologically active agenteffective amount of a composition as defined in claim 1; increasing intestinal absorption of said physiologically active agent; and modulating a physiological reaction or inducing an immune response in said human or animal.

Claim 24 (Withdrawn): Use of a composition according to claim 1 in the manufacture of a drug or a food for modulating a physiological reaction or inducing an immune response in human or animal.

Claim 25 (Withdrawn – Currently amended): A method for increasing the oral bioavailability of a physiologically active agent in a human or animal to modulate a physiological reaction or induce immune response,- said method comprising the steps of:

admixing said physiologically active agent with a dry blended homogenous composition; orally administering said mixture to said human or animal; , said composition comprising: a neutralizing agent in an amount sufficient to increase the pH to between pH 5 and pH 9 in the stomach of said human or animal; ground plant matter which comprises an inhibiting or of digestive enzymes to prevent enzymatic digestion of said agent in said digestive system; and allow delivering of said agent to the intestine; selected from ground bean seeds, ground oilseeds and ground pulse grains; an uptake increasing agent which increases intestinal absorption of said agent; , wherein said uptake increasing agent is selected from the group consisting of bile salt, saponin, deoxycholate, sodium lauryl sulphate, oleic acid, linoleic acid, monoolein, lecithin, lysolecithin, polyoxyethylene sorbitan ester, p-t-octylphenoxy polyoxyethylene, N lauryl β-D-maltopyranoside, 1-dodecylazacycloheptane-2-azone, and phospholipid; and orally administering said mixture to said human or animal and modulating a physiological reaction or inducing an immune response in said human or animal.

Claim 26 (Withdrawn-Currently amended): The method of claim 25, wherein said neutralizing results from administration of a neutralizing agent is at concentration between 10% to 60% w/w, said inhibition of digestive enzymes results from administration of a ground plant matter is at concentration between 1% to 50% w/w, and

said uptake increasing intestinal absorption results from administration of an uptake-increasing agent is at concentration between 0.1% to 50% w/w.

Claim 27 (Withdrawn – Currently amended): The method of claim 425, wherein said physiologically active agent is a vaccine.

Claim 28 (Withdrawn – Currently amended): The composition method of claim 275, wherein said neutralizing agent is in amount sufficient to neutralize acidic degradation in said human or animal fish-digestive system and allow delivery of said vaccine to the intestine of said human or animal fish.

Claim 29 (Withdrawn-Currently amended): The method of claim 25, wherein said neutralizing results from administering an agent is selected from the group consisting of anti-acids, sodium bicarbonate, sodium carbonate, sodium citrate, sodium hydrogen carbonate, calcium phosphate, calcium carbonate, magnesium carbonate, magnesium trisilicate, magnesium hydroxide, magnesium phosphate, bismuth subcarbonate, and combinations thereof.

Claim 30 (Withdrawn-Currently amended): The method of claim 26, wherein said neutralizing results from administering an agent which is at least one of sodium carbonate at a concentration of 10% to 20% w/w, and calcium carbonate at a concentration of 10% to 20% w/w of the composition.

Claim 31 (Withdrawn – Currently amended): The method of claim 254, further comprising the step of administering- at least one other ingredient selected from the group consisting of egg albumin, soybean, kidney bean, faba bean, rice bran, wheat bran, ethylenediamine tetraacetate (EDTA), albumin and ovalbumin.

Claim 32 (Withdrawn – Currently amended): A method of preventing degradation of a physiologically active agent to a human or animal by the intestine of the same to modulate a physiological reaction or induce immune response, comprising:
admixing said physiologically active agent with the composition of claim 1 and administering said physiologically active agent the same orally to said human or animal;
neutralizing the pH to between pH 5 and pH 9 in the stomach of said human or animal;
inhibiting digestive enzymes to prevent enzymatic digestion of said agent in said digestive system;
delivering said agent to the intestine;
increasing intestinal absorption of said agent; and
modulating a physiological reaction or inducing an immune response in said human or animal.